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Remarks:

Regarding the objections to claims 3, 4 and 10-12 under 37 CFR 1.75(c):

The applicant's amendments to claims believed to address and overcome the grounds of rejection.

Regarding the rejection of claim 5 under 35 USC 112, 2nd paragraph:

The applicant's amendments to claim 5 are believed to address and overcome the grounds of rejection.

Regarding the rejection of claims 1,3, 4, 10 and 12 under 35 USC 102(b) in view of Gamboa-Leon et al:

The applicant respectfully traverses the Examiner's rejection of claims 1 and 4 over the Gamboa-Leon reference, particularly in view of the currently amended claims.

Prior to discussing the merits of the Examiner's position, the undersigned reminds the Examiner that the determination of obviousness under §103(a) requires consideration of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. More recently in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the Supreme Court held that "A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results" and, later also held "If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, §103 likely bars its patentability."

A methodology for the analysis of obviousness was set out in *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000) A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by

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the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."

It must also be shown that one having ordinary skill in the art would reasonably have expected any proposed changes to a prior art reference would have been successful. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1207, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); In re O'Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); In re Clinton, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." In re Dow Chem. Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

However, an applicant may rebut a rejection based on 'obviousness' wherein it can be shown that there existed a substantial degree of unpredictability in the pertinent art area, particularly where there is evidence showing there is no reasonable expectation of similar properties in structurally similar compounds; see *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) See also *Ex parte Blattner*, 2 USPQ2d 2047 (Bd. Pat. App. & Inter. 1987)

The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of

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predictability. In particular, the court in *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 368-70 (CCPA 1971), stated:

"[i]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof."

The applicant asserts that applicant's presently claimed invention is properly considered unobvious over the prior art references of record. The applicant traverses the Examiner's grounds of rejection, and the Examiner's statement that:

10. One of ordinary skill In the art at the time the Invention was made, based on the teachings of Gamboa-Leon, would have found a compound differing by an additional – CH₂- in the length of the carbon chain (undecatrieneamide) compared with the prior art (decatrieneamide) obvious over the prior art. "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties." In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also in re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers prima facie obvious). In the instant case, there would have been a reasonable expectation that the additional –CH₂- of the claimed compound would not significantly after the properties of the prior art compound.

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The applicant points out that, at the threshold, a skilled artisan concerned with a flavoring compound would not consider the materials according to Gamboa-Leon which are isolates from a grass *Ctenium aromaticum*, used to produce a pungent, numbing sensation, hence the use in toothache. A skilled artisan would note these isolates are used to provide an local anesthetic effect, hence "... use of this grass for allaying toothache..." Gamboa-Leon's paper does not indicate, nor would provide a suitably skilled artisan, to consider its disclosure in view of a flavoring benefit. Although Gamboa-Leon mention

that isobutylamide pellitorine:

isoaffinin:

and, N-(1-isobutyl)-2,4,8,11-dodecatetraenamide:

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were among the isolates from Ctenium aromaticum, there is nothing further stated about these compounds other than they are useful for their local anesthetic effect. There is no reason why a skilled artisan would look to a local anesthetic in order to seek flavoring compounds. Further, although isobutylamide pellitorine, isoaffinin and N-(1-isobutyl)-2,4,8,11-dodecatetraenamide are mentioned as being Gamboa-Leon specifically notes that "Spectrally pure dodecadienamide caused numbing action on the gums and tongue; pure pellitorine is know to be tasteless but to produce a numbing sensation. (...)
Isoaffinin was not tested." From this statement, one of these three compounds was found

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to be tasteless, another only to provide a numbing action on the tongue, but no indication of taste is indicated, and the last was not tested. Presumably, Gamboa-Leon had no expectation of any difference in the properties of isoaffinin and expected it to be tasteless, but possibly have only a numbing effect. Thus, nothing in Gamboa-Leon provides any suggestion or reason why a skilled artisan would consider Gamboa-Leon's compounds in any flavoring application. It is thus properly considered a surprising that compounds according to the applicant's invention, particularly the compound

Should properly be considered nonobvious over the Gamboa-Leon's compounds.

Accordingly reconsideration of and withdrawal of the outstanding grounds of rejection is solicited.

Regarding the rejection of claim 2 under 35 USC 103(a) in view of Gamboa-Leon et. al., further in view of Fox et al.:

The applicants traverse the Examiner's rejection of claim 2 over the combined Gamboa-Leon and Fox references. The applicant's cancellation of claim 11 in this paper renders that objection moot.

For the sake of brevity the applicant herein incorporates all prior remarks concerning the Gamboa-Leon references as being similarly applicable to the current grounds of rejection.

In the current Office Action, the Examiner asserts that:

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15. The substitution of an -OH for an -H would be one that is readily apparent to one of ordinary skill in the art. As this change would alter the boiling point and water solubility of the compound, one of ordinary skill would make the substitution depending on the final use of the compound. This change would be within the abilities of one of ordinary skill, and would not require undue experimentation. The resultant compound would be expected to have a slightly altered boiling point and water solubility, and thus be more suitable for particular applications

The applicant traverses these assertions made by the Examiner as at the outset, it is well recognized in the art that flavor and fragrance chemistries are ones which are speculative in nature as even small changes in the structure of such molecules may have surprising and unexpected (and often unwelcome) effects.

With regard to the Examiner's position regarding the Fox reference, the applicant asserts there is no motivation with the combined Gamboa-Leon and Fox references for a skilled artisan to consider modifying the compounds in the manner suggested by the Examiner. While such a change would not, in hindsight, be difficult from an organic synthesis perspective, there is no reason why a skilled artisan would do so. Naturally any change to a chemical compound would likely result in a change in one or more of its physical properties, e.g., boiling point, water solubility, but such are not proper or relevant motivations for a skilled artisan considering the effects on flavoring properties which may be wholly unrelated to the boiling point, water solubility, etc. of a compound. The fact of the matter is that although Gamboa-Leon discloses and, N-(1-isobutyl)-2,4,8,11dodecatetraenamide, and that "Spectrally pure dodecadienamide caused numbing action on the gums and tongue; ... " Gamboa-Leon provides no indication why such a compound would be chosen or suitable as a starting material for a flavoring compound as Gamboa-Leon mentions no such flavoring character to that compound. Additionally there is no reason, even if one were to start with this compound, why it should be modified and which modification should be made to the compound in order to achieve a

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compound which has a flavoring benefit. The Examiner's position that the substitution of —H with —OH would be obvious is unsupported; that first, there is no reason why a skilled artisan would have any motivation to do so, and second, that there would be no reasonable expectation of any likelihood of imparting flavoring properties to the molecule. Thus, the applicant asserts that the Examiner's position in based on an impermissible "hindsight reconstruction" of the prior art which is based on a "picking-and-choosing" amongst isolated parts of the prior art wherein there is (a) no motivation to do so, and where there is (b) no reasonable likelihood of success from such changes. The Examiner is reminded that in *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992), the Federal Circuit stated:

"It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." (quoting *In re Fine*, 837 F.2d at 1075, 5 USPQ2d at 1600)

See also W.L. Gore & Associates, Inc. v. Garlock, Inc. 220 USPQ 303 (CAFC, 1983); In re Mercier 185 USPQ 774, 778 (CCPA, 1975); In re Geiger 2 USPQ2d 1276 (CAFC, 1987).

Thus, the applicant is of the opinion that the Examiner's rejection is improper and should be withdrawn.

Regarding the rejection of claims 5-9 under 35 USC 103(a) in view of Gamboa-Leon in view of US 3720762 to Hatasa:

The applicant traverses the rejection of claims 5-9 in view of the combined Gamboa-Leon and Hatasa references.

The Examiner asserts that:

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ordinary skill would have had a reasonable expectation that the isoaffinin would have the same flavor and elight numbing properties as the spitanthol, another isobutylamide of an unsaturated fatty acid. Substitution of one compound for another would not require undue experimentation, and there would have been a reasonable expectation that the resultant foods, beverages and oral care products would maintain their favorable organoleptic properties.

The applicant traverses the Examiner's basis for the rejection. The structures of Gamboa-Leon's N-(1-isobutyl)-2(E),4(E),8-decatrienamide:

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and Hatasa's spilantol compound:

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As the Examiner admits, Gamboa-Leon fails to disclose the utility of the N-(1-isobutyl)-2(E),4(E),8-decatrienamide in any foodstuffs or beverages. The Examiner also admits that Hatasa's spilanthol compound is also known to provide a sharp flavor and an anesthetic property. The applicant however traverses the Examiner's statement that as spilanthol is noted to have a "sharp flavor and an anesthetic property" that

isoaffinin:

would be expected to have a flavoring benefit as N-(1-isobutyl)-2(E),4(E),8-decatrienamide is an isobutylamide of an unsaturated fatty acid. First, as is noted above,

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it is well recognized in the fragrance and flavoring art that, even minor changes in the molecular structure of a compound may introduce unexpected effects which are not predictable. Second there is not basis why Hatasa's spilantol compound which has a clearly distinguishable chemical structure from that of isoaffinin as well as N-(1-isobutyl)-2(E),4(E),8-decatrienamide would be expected to impart to the isoaffinin as well as N-(1-isobutyl)-2(E),4(E),8-decatrienamide a flavoring characteristic, particularly where no such flavoring characteristic is stated by Gamboa-Leon. Thus, the only fair inference or teaching to be gleaned is that what is actually taught by the prior art, as, for reasons discussed above and more thoroughly discussed in applicant's prior Amendment of 09.July.2008, it is well recognized that the relevant art is highly unpredictable.

In view of the foregoing remarks, reconsideration of the rejections raised by the Examiner is respectfully requested, and early issuance of a *Notice of Allowance* is solicited.

Should the Examiner in charge of this application believe that telephonic communication with the undersigned representative would meaningfully advance the prosecution of this application towards allowance, the Examiner is invited to contact the undersigned at their earliest convenience.

PETITION FOR A THREE-MONTH EXTENSION OF TIME

The applicant respectfully petitions for a three-month extension of time in order to permit for the timely entry of this response. The Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263 with respect to this Petition.

CONDITIONAL AUTHORIZATION FOR FEES

Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

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Respectfully Submitted;

Andrew N. Parfomak, Esq. Date:

Reg. No. 32,431

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Enclosures - as indicated

CERTIFICATE OF TELEFAX TRANSMISSION UNDER 37 CFR 1.8

I certify that this document, and any attachments thereto, addressed to the: "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" is being telefax transmitted to (571) 273-8300 at the United States Patent and Trademark Office.

Allyson Ross

Date

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